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Summary of Recent Assay Changes for Hepatitis B Surface Antigen (HBsAg) and Detection of Cytomegalovirus (CMV) Antibodies

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Summary:
Changes to the following assays have been implemented at CPAL in order to effect technical improvements in the performance characteristics of each.

Hepatitis B Surface Antigen (HBsAg) in Serum and Plasma

Effective March 1, 2007, CPAL is using the Genetic Systems HBsAg EIA (3.0) kit and the Genetic Systems HBsAg Confirmatory Assay 3.0 in replacement of the Ortho HBsAg ELISA Test System 3. This assay will continue to be routinely performed on the Ortho Summit processor platform. The study of performance characteristics and successful validations were completed in February. All comparison studies performed as expected.

Detection of Cytomegalovirus (CMV) Antibodies

Since August 30, 2006, detection of Cytomegalovirus (CMV) has been performed using the *Immucor Capture-CMV* test kit. The *Immucor Capture-CMV* is an in vitro qualitative solid phase red cell adherence test system for the detection of antibodies (IgG plus IgM) to cytomegalovirus (CMV) in human serum or plasma. Capture-CMV is intended to be used in screening of donors or patients for serological evidence of previous infection by CMV. The CMV antigen utilized in this test is obtained from the cytomegalovirus strain AD 169 grown in human foreskin (HF) fibroblast cells.

This assay replaced the Becton-Dickinson (BD) CMVscan Latex Agglutination Test for Detection of Antibodies to Cytomegalovirus (CMV) assay. The study of performance characteristics and successful validations of the *Immucor Capture-CMV* test kit were completed in August 2006. All comparison studies performed as expected.

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